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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,677	03/24/2000	SVEND BIRKELUND	BIRKELUND=1	2720

1444 7590 11/15/2006

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,677	BIRKELUND ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,10,13 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5* is/are allowed.

6)☒ Claim(s) *10,13 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: attachment of IFW scanned 1449, refrence AN considered.

RESPONSE TO AMENDMENT

The amendment filed 8-31-06 has been entered into the record. Claims 1, 10, 13 and 18 are pending.

The letter of September 28, 2006 has been entered into the record. The letter references an IDS filed June 22, 2002. It is noted that there is no IDS of record filed June 22, 2002. It appears that Applicant is referencing the IDS of June 22, 2000. Attached hereto is the initialed IDS of June 22, 2000 as it appears in the electronic record. The record indicates that reference AN on the IDS of June 22, 2000 was initialed by the previous examiner of record.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Any objection or rejection not reiterated herein is withdrawn based on Applicants amendments.

Election/Restrictions

Claim 5 is directed to a technical feature free of the prior art. Pursuant to the procedures set forth in the MPEP, claims 13 and 18 are directed to the process of using or making an allowable product, previously withdrawn from consideration as a result of a lack of unity, claims 13 and 18 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the lack of unity as set forth in the Office action mailed on 9-27-01 is hereby withdrawn.** In view of the withdrawal of the requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

New Rejections Based on Amendment

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 13 and 18, recites " a or an protein of claim 5", however claim 5 as amended now only recites one protein. "A" is indefinite in this position because it implies alternatives that no longer exist, in the amended claim. This issue may be resolved by amending the claim to recite "the protein of claim 5".

As to claim 13, the claim is prima facie indefinite in that it does not teach how the protein is used in the method. Further, the term "immunizing a mammal against Chlamydia pneumpniae" is unclear because it is unclear if a vaccine or immunogenic response is required. The skilled artisan would be unable to interpret the metes and bounds of this language because it does not provide for the requisite outcome, (e.g. immune response or protective immune response)

As to claim 18, the claim is incomplete because it is missing a step of detecting binding of the protein with a component of the sample because the correlation is a mental step of assessing the outcome of a process step that is not positively recited in the method. The claim is also confusing in the recitation of "species specific method of identifying infection of a mammal" because it is unclear if the species specific references the recitation of mammal or references *Chlamydia pneumoniae*. This issue might be resolved by amending the preamble to recite "A method of identifying a *Chlamydia pneumoniae* infection in a mammal, said method comprising:".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is drawn to a process of use without any positively recited method steps. The absence of any positively recited method steps renders the subject matter non-statuatory. "Use of" is not an actively recited method step.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating an immune response in a mammal comprising administering an immunologically effective amount of the protein of claim 5 it does not reasonably provide enablement for vaccines as implied by the language of "immunizing against *Chlamydia penumoniae*." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The teachings of the specification are limited to using the protein of the invention to generate an immune response in mammal to generate antibodies for diagnostic use. The phrase "immunizing against *Chlamydia pneumoniae*" has been interpreted as a method of vaccinating for purposes of this rejection because the language is not defined in the specification as originally filed.

The dictionary definition of vaccine is "A prophylactic or therapeutic material containing antigens derived from one or more pathogenic organisms which, on administration to man or animal, will stimulate active immunity and protect against

infection with these or related organism (i.e. produce protective immunity)." (The Dictionary of Immunology, Herbert et al eds, Academic Press, 1995) would clearly realize the critical deficiency of this specification with respect to vaccines. There is absolutely no demonstration of protective immunity upon administration in any animal model of disease. Such is required by the common meaning as demonstrated by the dictionary definition and is reiterated in Plotkin et al. The art is replete with evidence that the ability to produce an antibody (immunogenicity) is insufficient to correlate with protection from infection. See for example Feng et al (Infection and Immunity, 64(1):363-365, 1996) that teaches that P55, is an immunogenic but nonprotective 55-kilodalton *Borrelia burdorferi* protein in murine lyme disease. As such, one skilled in the art would have ample reasons to doubt the ability to use the claimed protein or composition comprising the protein as a vaccine. The specification fails to teach that any immune response generated upon injection by the claimed protein provide for protection against infection. Vaccines by definition trigger an immunoprotective response in the host vaccinated and mere antigenic response is insufficient. It is well recognized in the vaccine art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity and that the ability to generate of antibodies is not necessarily correlative of protective immunity (Chandrashekar et al US Patent 6,248,329, col. 1. lines 35-42) and (Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, S.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". The art teaches that the selection of protective antigens from the plethora of protein antigens available is unpredictable. The specification fails to that the presence of antibodies that bind the protein as claimed provides for protection from infection. The art does not recognize any homologs as therapeutic vaccines capable of conferring

protection in an immunized mammal. The specification fails to teach that the claimed protein is able to perform as a vaccine (i.e. protection, reduction in morbidity and/or mortality of disease). The courts have held that it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. (Genentech Inc. v. Novo Nordisk A/S Ltd., 42 USPQ2d 1001). Moreover, the specification must have been enabling at the time the invention was made and developments after the time of filing are of no consequence to what one skilled in the art would have believed at the time of filing (*In re Wright*, 27 USPQ2d 1510). In the absence of a teaching of the claimed polypeptides are effective in prevention of disease, the specification is not be enabled for vaccines. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The description of the specification is to a description that antibodies in serum samples do not detect antigens of 98kDa in either *Chlamydia trachomatis* or *Chlamydia psittaci* (see page 5, lines 11-20). The claims are directed to "components of said sample" where the sample is of a biological fluid or tissue. The specification does not teach what the other components are or how to detect their binding. The genus term "components" is inclusive of other proteins of unidentified structure, positive and negative ions, and carbohydrates of undefined and unidentified structure. The specification does not teach what these other components are or how to detect binding of the components or how they distinguish *C. pneumoniae* from other species. The specification does not place any

structure, chemical or functional limitations on the variants of "components". The recitation of "component" does not convey a common structure or function. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure fails to describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of the binding of alone is insufficient to describe the genus of "components" that function equivalently. One of skill in the art would reasonable conclude that the disclosure of an antibody, fails to provide a representative number of species of binding components sufficient to describe the claimed genus of components. Applicants were not in possession of the claimed genus because the specification does not convey to one of skill in the art a representative number of variants in structure and function of any such polypeptide that has the claimed/structure and function. The genus of components is substantial and highly variant because the polypeptides do not have a common structure and function. As such the specification lacks written description for the highly variant genus of binding components and one skilled in the art would not recognize that applicants had possession by identification of the genus components useful for identifying infection in the assay as instantly claimed.

Status of Claims

Claim 5 is allowed. Claims 10, 13 and 18 stand rejected.

Suggestion for Allowable Language

Claim 10. A composition comprising the protein of claim 5 and a pharmaceutically acceptable carrier.

Claim 13. A method of generating an immune response in a mammal comprising administering to the mammal an immunologically effective amount of the protein of claim 5.

Claim 18. A method of identifying a *Chlamydia pneumoniae* infection in a mammal, said method comprising:

(a) obtaining a sample comprising antibodies from the mammal,

(b) contacting said sample with a diagnostic reagent, said reagent comprising the protein of claim 5 in labeled or immobilized form,

(c) detecting binding of antibodies in the sample with the diagnostic reagent, and

(d) correlating the presence of binding of said protein with antibodies in said sample with the presence of an infection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy
Primary Examiner
Art Unit 1645